IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
No. 5:10-MD-1500-H(3)

SUNOVION PHARMACEUTICALS, INC., et al.,	)	
Plaintiffs,	)	
v.	)	Eastern Division No. 4:08-CV-89-H(3)
SANDOZ, INC.,	)	
Defendant.	)	

ORDER

This matter is before the court on a motion to dismiss for lack of subject matter jurisdiction filed by defendant Sandoz, Inc. ("Sandoz") [DE #275], as well as defendant Sandoz's appeal of an order extending the thirty-month stay of FDA approval [DE #304]. On December 3, 2010, United States Magistrate Judge William A. Webb issued a Memorandum & Recommendation/Order recommending denial of Sandoz's motion to dismiss. Judge Webb further determined that Sandoz had failed to cooperate reasonably in expediting the litigation and extended the thirty-month stay of FDA approval for a period of sixty days. Sandoz has filed written objections to the recommended decision and order, plaintiffs have responded, and both parties have

submitted supplemental briefs on the jurisdictional issue as requested by the court.

STATEMENT OF THE CASE

Sepracor, Inc.,[1] together with UCB, S.A., and UCB, Inc. ("UCB") initiated this action against Sandoz upon filing a one-count complaint alleging infringement of U.S. Patent No. 5,698,558 ("the '558 patent"). The '558 patent is a method-of-use patent claiming use of levocetirizine dihydrochloride 5 mg tablets ("levocetirizine") in the treatment of seasonal and perennial allergic rhinitis. Plaintiffs are the record owner and exclusive licensee of the '558 patent. On May 25 2007, the United States Food and Drug Administration ("FDA") approved plaintiff's New Drug Application to market XYZAL® (levocetirizine) for the treatment of seasonal and perennial allergic rhinitis, as well as urticaria (commonly known as hives).

In or around May 2008, Sandoz filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic levocetirizine prior to expiration of the '558 patent. Originally, Sandoz sought approval of its generic levocetirizine

[1]Sepracor, Inc., is the predecessor in interest to plaintiff Sunovion Pharmaceuticals, Inc. ("Sunovion"). By order entered February 9, 2011, Sunovion was substituted as a party and the caption was changed to reflect the substitution. (See Feb. 9, 2011 Order [DE #323].)

for both FDA-approved uses: (1) treatment of allergic rhinitis; and (2) treatment of urticaria. For the first use, Sandoz included a paragraph IV certification asserting that plaintiffs' patent was invalid, unenforceable or would not be infringed. Because urticaria is not an indication claimed by the '558 patent, Sandoz filed a section viii statement declaring that intended use is not covered by the '558 patent.

On February 5, 2010, Sandoz submitted to the FDA a proposed amendment of its ANDA "revising its patent certification from a paragraph IV to a section viii statement." Sandoz informed the FDA that it was no longer seeking approval of its generic levocetirizine for treatment of allergic rhinitis, the only use covered by the '558 patent. Sandoz asserts that this amendment divested the court of subject matter jurisdiction over plaintiffs' infringement claim and that dismissal is, therefore, required.

COURT'S DISCUSSION

I. Standard of Review

Before this court for review are two separate matters: Judge Webb's M&R concerning Sandoz's motion to dismiss and Judge Webb's order extending the thirty-month stay of FDA approval. Judge Webb's recommended decision is subject to de novo review. See 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3). However,

his order extending the FDA stay may be overturned only if clearly erroneous or contrary to law. See Fed. R. Civ. P. 72(a). "A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." United States v. U.S. Gypsum Co., 333 U.S. 364, 395 (1948).

II. Sandoz's Motion to Dismiss

Sandoz objects to the M&R, contending that its ANDA, as amended, does not seek approval for any patented indications and that jurisdiction over plaintiffs' action is therefore lacking. Sandoz does not dispute that subject matter existed at the outset of plaintiffs' action. (See DE #276 at 5.) However, Sandoz argues that its amendment to the ANDA carved out the patented use, thereby divesting this court of subject matter jurisdiction.

Jurisdiction over patent infringement actions is conferred upon the United States District Courts by virtue of 28 U.S.C. § 1338, which provides that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents." 28 U.S.C. § 1338(a). Section 1338(a) jurisdiction extends "to those cases in which a well-pleaded complaint establishes either that federal patent law

creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 808-09 (1988).

Title 35, United States Code, Section 271(e)(2) is an Act of Congress relating to patents. It is not a jurisdictional statute, but it does act to confer jurisdiction pursuant to § 1338(a). Section 271(e)(2) creates an artificial, defined act of infringement sufficient to create case or controversy jurisdiction, thereby enabling court resolution of issues concerning the validity or infringement of a patent prior to a generic company's infringement of the patent. Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1330 (Fed. Cir. 2003); Glaxo, Inc. v. Novopharm, Inc., 110 F.3d 1562, 1569 (Fed. Cir. 1997). "In short, section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed." Allergan, 324 F.3d at 1330.

Sandoz argues that without a paragraph IV certification, there is no § 271(e)(2) infringement and, therefore, no jurisdiction over plaintiff's infringement claim. However,

Sandoz fails to recognize that plaintiffs' infringement claim is not premised solely upon § 271(e)(2) - it also asserts alternative theories of recovery under 35 U.S.C. § 271(a), (b), (c), and (f). (See Compl. [DE #1] ¶ 24.) Each of these alternative theories also arises under federal patent law. Consequently, subject matter jurisdiction exists over plaintiffs' infringement claim notwithstanding any dispute as to the viability of plaintiffs' theory that Sandoz violated § 271(e)(2).

III. Extension of the Thirty-Month Stay

Sandoz also objects to Judge Webb's order extending the thirty-month stay of FDA approval based upon a finding that Sandoz had failed to reasonably cooperate in expediting the litigation. Sandoz argues this is reversible error, asserting (1) lack of subject matter jurisdiction; (2) a stay is no longer applicable because the only basis for the stay was Sandoz's paragraph IV certification, which has now been withdrawn; and (3) the facts upon which Judge Webb based his decision do not warrant an extension of the stay.

Title 21, United States Code, Section 355(j)(2)(B)(iii) imposes an automatic, thirty-month stay of FDA approval of a generic drug where the ANDA applicant made a paragraph IV certification and the patent holder brings an infringement suit

within forty-five days of notice of the certification. 21 U.S.C. § 355(j)(2)(B)(iii). District courts have discretion to adjust the statutory thirty-month stay if "either party to the action failed to reasonably cooperate in expediting the action." Id. However, such adjustments are the exception, not the norm. See, e.g., In re Brimonidine Patent Litig., No. 07-MD-1866-GMS, 2008 WL 4809037 (D. Del. Oct. 31, 2008) (insufficient showing to toll thirty-month stay); Novartis Corp. v. Dr. Reddy's Labs., Ltd., No. 04-CV-757-SAS, 2004 WL 2368007 (S.D.N.Y. Oct. 21, 2004) (extending thirty-month stay where ANDA applicant requested stay of litigation); Minnesota Mining & Mfg. v. Alphapharm, No. 99-CV-313, 2002 WL 1299996 (D. Minn. Mar. 8, 2002) (denying motion to stay where FDA approval already obtained).

The stay authorized by 21 U.S.C. § 355(j)(2)(B)(iii) applies only where an ANDA contains a paragraph IV certification. In light of Sandoz's withdrawal of its paragraph IV certification, plaintiffs were not entitled to an extension of the the thirty-month stay. In the event Sandoz is subsequently required to amend its section viii statement to a paragraph IV certification, plaintiffs may be entitled to an additional stay or injunctive relief delaying FDA approval.

Absent such a determination, however, no basis exists for extending the stay of FDA approval.

CONCLUSION

For the foregoing reasons, the court DENIES Sandoz's motion to dismiss for lack of subject matter jurisdiction [DE #275] and VACATES the December 3, 2010, order extending the thirty-month stay of FDA approval.

This 1st day of September 2011.

MALCOLM J. HOWARD
Senior United States District Judge

At Greenville, NC
#31